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K112868- Dreamgard Nightguards; Replacement page

IX. 510(K) SUMMARY

The 510(k) Summary for the company's device is provided herewith.

Dreamgard, Inc., Dreamgard nightguards

Submitters Name, Address, Telephone Number, Contact Person and Date Prepared

Dreamgard, Inc.
6801 Flying Cloud Drive
Eden Prairie, MN 55344

Contact Person: Steve Washburn, President/CEO
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Email: swashburn@dreamgard.com

Consultant: Suzan Onel
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Date Prepared: December 12, 2011

Name of Device

Dreamgard™ REM-SOFT
Dreamgard™ REM-LITE
Dreamgard™ REM-ULTRA
Dreamgard™ REM-MAX

Name/Address of Sponsor

Dreamgard, Inc.
6801 Flying Cloud Drive

Eden Prairie, MN 55344

Contact Person: Steve Washburn, President/CEO
Phone: 612.360.7609
Email: swashburn@dreamgard.com

Common or Usual Name

Dental Protector/Nightguard

Classification

Unclassified

Product Code

MQC

Predicate Devices

Device	Applicant	510(K)
Dental Concepts Bite Plate	Dental Concepts	K024261
Myohealth Clenching Inhibitor	MCI-Myohealth Systems	K040315

Intended Use / Indication for Use

Dreamgard nightguards are indicated for protection against bruxism (nighttime teeth grinding) and jaw clenching during sleep, short-term pain relief from muscle spasm due to occlusal interference, and prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the posterior mandibular and maxillary teeth by the temporalis muscle. Dreamgard nightguards are for prescription use only.

Technological Characteristics

The Dreamgard REM-SOFT, REM-LITE, REM-ULTRA and REM-MAX nightguards are composed of a soft, clear material made of thermoplastic resins. The devices are custom fabricated for each patient by taking an impression of the patient's upper teeth and using that impression to create a dental model to then fabricate a multi-layer custom nightguard using a pressure thermo-forming machine. The nightguard is designed to fit on the upper teeth and to span from 2nd molar to 2nd molar.

The four versions of the Dreamgard nightguards differ in thickness based on the number of layers of thermoplastic resin used. The final custom product has a soft, comfortable inner

layer and a harder protective outer layer. The dentist delivers the nightguard to the patient and provides final fitting and bite balancing adjustments by using the "boil and bite" method to mold the fit to the patient's teeth and bite.

Performance Data

No performance data is required in support of this 510(k) notice.

Biocompatibility

The Dreamgard REM-SOFT, REM-LITE, REM-ULTRA and REM-MAX nightguard materials contact the mouth surfaces in fitting and use. The constituent materials are composed of thermoplastic resins, all of which are commonly used materials in nightguards, mouthguards, and other FDA cleared dental devices. Biocompatibility testing show that the materials used to fabricate the Dreamgard Nightguards are safe and pose no health risk.

Substantial Equivalence

The Dreamgard REM-SOFT, REM-LITE, REM-ULTRA and REM-MAX nightguards are substantially equivalent to the identified predicate devices. The intended uses and indications for use are virtually identical to the predicate devices, which are all sold as prescription devices. The Dreamgard nightguards and the predicate devices are also similar in purpose and functionality and with regard to physical composition, technological characteristics, design, and principles of operation. All devices are composed of thermo-formable resins.

The Dreamgard nightguards and the MCI Clenching Inhibitor (K040315) are both custom fabricated by the dentist using standard industry impression material and tray. The impression is converted into a dental mold by a dental laboratory which is then used to fabricate a custom nightguard composed of multiple layers of thermoplastic resins commonly used in dental protectors, nightguards, and mouthguards. The final Dreamgard product is customized to the natural bite of the patient in the same manner the Dental Concepts Bite Plate (K024261), i.e., it is molded by heating in hot water and having the patient bite down on it. These differences in fabrication and fitting do not significantly affect safety or effectiveness. All three products have substantially equivalent directions for use for the patients. Both the Dreamgard nightguards and the Dental Concepts Bite Plate fit across the entire span of upper teeth (from 2nd molar to 2nd molar). While the Myohealth device is designed to span 6 teeth (from upper cuspid to cuspid), all three devices are of comparable size and thickness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dreamgard, Incorporated
C/O Ms. Suzan Onel
Consultant
K&L Gates LLP
1601 K Street, NW
Washington, District of Columbia 20006

JAN 19 2012

Re: K112868
Trade/Device Name: Dreamgard Nightguards
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MQC
Dated: January 9, 2012
Received: January 11, 2012

Dear Ms. Onel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112868

Indications for Use Statement

510(k) Number (if known):

Device Name: Dreamgard nightguards

Indications For Use:

Dreamgard nightguards are indicated for protection against bruxism (nighttime teeth grinding) and jaw clenching during sleep, short-term pain relief from muscle spasm due to occlusal interference, and prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the posterior mandibular and maxillary teeth by the temporalis muscle

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K112868